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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,320	05/29/2002	Adriano Cocola	70479	1540
23872	7590	04/05/2004		
MCGLEW & TUTTLE, PC 1 SCARBOROUGH STATION PLAZA SCARBOROUGH, NY 10510-0827			EXAMINER PAIK, STEVE S	
			ART UNIT	PAPER NUMBER
			2876	
DATE MAILED: 04/05/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/088,320

Applicant(s)

COCOLA ET AL.

Examiner

Steven S. Paik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5-12 and 21-28 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-3, 5-12 and 21-28 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 29 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

1. Receipt is acknowledged of the Amendment filed December 12, 2003. The Amendment includes cancellation of claims 4 and 13-20 and addition of new claims 21-28. The Amendment further includes changes to claims 1-3 and 6-12 to improve the form and to clarify the claimed invention.

### ***Specification***

2. The disclosure is objected to because of the following informalities: The application is required to insert a paragraph including a continuing data such as "This application is a 371 of PCT/1T00/00359 filed on September 12, 2000" immediately following the title of the invention. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 5-12, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaffin, III et al. (USPN 3,831,006) in view of Knepple et al. (WO 99/41014, Abstract).

Re claims 1, 23, and 25 Chaffin, III et al. disclose a patient-specimen identification system (Fig. 1) and method for data management in an analytical laboratory. The method comprises the steps of providing a plurality of containers (sample container 15/sub-sample

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containers 23) for laboratory analysis of biological specimens, each container being associated with a unique identification code (16 or 24), associating a patient code (12) with a patient to be subjected to analysis, for each container used for said patient, generating in a data processing system (logic 32 and memory 13) a combination (at steps 17, 20, and 21) of said patient code (12) and said identification code (16) of the corresponding container, providing, at a second location, (col. 6, lines 63+ discloses that samples are taken at one location and the container with a unique identification label associating with a patient code is processed at another location) a biological specimen from the patient with the associated patient code in the container with the unique identification code, providing correlation data (via memory 13), based on combination of the patient code and the unique identification code of the container read and stored in a portable temporary memory, and carrying out, by means of at least one analyzer (27), at least one analysis on the container or containers used for said patient, the analyzer entering the results of said analysis, combined (at memory 13) with the identification code of the container (15) or containers (23), into the data processing system (logic 32 and memory 13).

Chaffin, III is silent about a unique identification code being applied on said container during the production or packaging of the container, and the identification code being a barcode.

Knepple et al. disclose a sample containers (10) used in an analysis device including a machine-readable identification label (12, barcode, page 6, line 17) applied during production (10a in the Figure) of the sample container. Since the unique identification code (barcode) is applied during the production process, a lab technician does not have to print and affix a separate machine-readable label on a sample container. This process obviously saves time and

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eliminates a chance of erroneously applying a machine-readable label to a wrong sample container.

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention was made to incorporate the method of applying a unique machine-readable identification code (12 barcode) to a sample container (10) during the production process (10a), as taught by Knepple et al., to the patient-specimen identification system of Chaffin, III et al. for the purpose of simplifying the steps of analysis in a laboratory by eliminating the process of generating a unique machine-readable label for each sample container and affixing the label to a corresponding sample container. Furthermore, such modification of using a sample container with a unique machine-readable code label applied during production obviously prevents a lab technician from erroneously mixing the label and the sample container.

Re claim 2, Chaffin, III et al. in view of Knepple et al. disclose the method as recited in rejected claim 1 stated above, further comprising the steps of:

generating a patient code (col. 3, ll. 1-10) for at least one patient on whom at least one analysis is to be carried out and storing said patient code in a data processing system (patient information is stored at memory 13 of a data processing system comprising logic 32 and memory 13);

placing a biological specimen from said patient in said at least one container (col. 3, ll. 17-23);

carrying out at least one analysis of said specimen in at least one analyzer (27), the analyzer reading the identification code of said container (via reader #3) and entering into said

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data processing system the results of the analysis (test results) combined with the identification code (16 or 24) of said container;

using said data processing system (logic 32 and memory 13) to associate the results of the analysis or analyses with the patient code (12), and then with the patient identified by the patient code, by means of the combination of the patient code with the identification code.

Re claims 3 and 5, Chaffin, III et al. in view of Knepple et al. disclose the method as recited in rejected claim 1 stated above, where said identification code (16 or 24) is placed on the corresponding container in a machine readable format (col. 3, ll. 23-30 and ll. 61-64).

Re claims 6 and 7, Chaffin, III et al. in view of Knepple et al. disclose the method as recited in rejected claim 3 stated above, in which the combination of the patient code (12) with the unique identification code (16 or 24) is generated by the sequential reading by an automatic reading instrument (reader #1-3) of the patient code and the unique identification code, or vice versa.

Re claim 8, Chaffin, III et al. in view of Knepple et al. disclose the method as recited in rejected claim 1 stated above, in which said patient code (12) is generated by a central computer of said data processing system; the combination of the patient code (12) with the unique identification code (16 or 24) is carried out by means of a unit (13) of said data processing system other than said central computer; and the result of the analysis, associated with the patient code is sent to said central computer (col. 4, ll. 45-53).

Re claim 9, Chaffin, III et al. in view of Knepple et al. disclose the method as recited in rejected claim 1 stated above, in which said patient code (12) is generated by a central computer of said data processing system; the combination of the patient code (12) with the identification

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code (16 or 24) is carried out by means of a unit (13) of said data processing system other than said central computer; and the result of the analysis, associated with the patient code is sent to said central computer (col. 4, ll. 45-53), the central computer being programmed to associated with the result of the analysis the data relating to the patient to whom said results relates (the logic 32 may comprises any digital computers or any dedicated logic/memory unit. In a computer system having a network, which is in common in a laboratory or hospital system, it is inherent to designate a computer as a main or a central computer or database server to perform data management.).

Re claim 10, Chaffin, III et al. disclose a data managing system (Fig. 1) for data management in an analytical laboratory. The system comprises a central electronic computer (col. 4, ll. 45-53), for acquiring the data on patients (10) on whose biological specimens (such as blood) the analyses are to be carried out, and for generating a patient code (12) for each patient acquired, means for acquiring (readers #1-3) a unique identification code (16 or 24) associated with each container (15 or 23) of a plurality of containers for laboratory analysis of biological specimens, means for combining (memory 13) each of said acquired unique identification codes with a corresponding patient code, and at least one analyzer (27) with means for reading identification code (via readers #2 and #3) associated with the containers which are placed in it, said analyzer carrying out at least one analysis on a biological specimen contained in the containers placed in it and supplying to said electronic computer (logic 32) the results of the analyses carried out, combined with data capable of associating said result (test results) with the patient (10) whom the biological specimen belongs.

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Chaffin, III is silent about a unique identification code being applied on said container during the production or packaging of the container, and the identification code being a barcode.

Knepple et al. disclose a sample containers (10) used in an analysis device including a machine-readable identification label (12, barcode, page 6, line 17) applied during production (10a in the Figure) of the sample container. Since the unique identification code (barcode) is applied during the production process, a lab technician does not have to print and affix a separate machine-readable label on a sample container. This process obviously saves time and eliminates a chance of erroneously applying a machine-readable label to a wrong sample container.

Hence, it would have been obvious to a person having ordinary skill in the art at the time of the invention was made to incorporate the method of applying a unique machine-readable identification code (12 barcode) to a sample container (10) during the production process (10a), as taught by Knepple et al., to the patient-specimen identification system of Chaffin, III et al. for the purpose of simplifying the steps of analysis in a laboratory by eliminating the process of generating a unique machine-readable label for each sample container and affixing the label to a corresponding sample container. Furthermore, such modification of using a sample container with a unique machine-readable code label applied during production obviously prevents a lab technician from erroneously mixing the label and the sample container.

Re claim 11, Chaffin, III et al. in view of Knepple et al. disclose the system as recited in rejected claim 10 stated above, further comprising means for receiving (memory 13) from said at least one analyzer (27) the result of said at least one analysis (test results) combined with the unique identification code (16 or 24) of the container in which the analyzed biological specimen

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is placed, said means being programmed to associate said result with the patient code (12) relating to the identification code combined with the result of the analysis, to send the result analysis combined with the patient code to and central electronic computer (logic 32; col. 4, ll. 45-53).

Re claim 12, Chaffin, III et al. in view of Knepple et al. disclose the system as recited in rejected claim 10 stated above, in which the result of the analysis, combined with the unique identification code (16 or 24) of the corresponding container (15 or 23), is sent to said central computer (via memory 13), the central computer (logic 32; col. 4, ll. 45-53), the central computer being programmed to associate, by means of the combination of the patient code (12) with the identification code, each unique identification code and - consequently the result of the analysis - with the patient code of the patient whose biological specimen is contained in the container identified by said identification code.

5. Claims 21, 22, 24, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaffin, III et al. (USPN 3,831,006) as modified by Knepple et al. (WO 99/41014, Abstract) as applied to claims 1-3 and 5-12 above, and further in view of Carr et al. (USPN 5,888,825).

Re claims 21, 22, 24, and 26-28, Chaffin, III et al. disclose a sample container (15) or sub-sample containers (23) having a unique machine-readable label (16 or 24) for each of the sample container or sub-sample containers. The labels are machine-readable labels for a patient-specimen identification system. The coding on the labels comprises a fourteen-hole pattern representing four octal digits, two label identification bits, and two parity bits. Furthermore, Chaffin, III et al. teach or suggest that any other type of label or coding system not excluding a

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barcode, may be used with the patient-specimen identification system. Chaffin, III in view of Knepple et al. further discloses the container including a machine readable code during production or packaging for achieving aforementioned advantages.

However, Chaffin, III or Knepple is silent about the feature concerning means for determining an expiry date.

Carr et al. disclose a sample bottle (602 in Fig. 3) typically contains a blood or other sample to be monitored for microorganism content. The bottle includes a unique barcode (616) comprising an individual number, plus batch code and expiry data information. As appreciated by an artisan of ordinary skill in the art, a barcode may contain any encoded information in accordance with a user's need. For example, a barcode used in a library system mostly would contain information about a book, a publisher, and circulation data, etc. Another barcode used in a grocery store obviously contains information about a product or good, price, and promotions, etc. Furthermore, it is well-known that a biological sample in a laboratory would have a predetermined expiration date to prevent the sample from being contaminated after a period of time.

### ***Response to Arguments***

6. Applicant's arguments filed December 12, 2003 have been fully considered but they are not persuasive.

### **Rejections under 35 U.S.C. § 102 (b)**

The applicant amended the independent claims 1 and 10 to include additional limitations such as "a unique identification code of said container and having a marking including said unique identification code applied to said container during production or packaging of said

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container” and “ a marking with said unique identification code, said marking being applied to said container during production or packaging of the container;”. The applicant’s argument regarding claims 1-3, 5, 6, 8-13 and 17 on pages 13-15 fails to show what are missing or not disclosed in Chaffin, III (USPN 3,831,006) reference. Rather, the applicant amended the claims by combining limitations in a dependent claim (Previously rejected under 35 U.S.C. § 103(a)). Therefore, the argument regarding rejected claims 1-3, 5, 6, 8-13 and 17 under 35 U.S.C. § 102 (b) is not persuasive.

Furthermore, on page 14, the applicant stated that each container or tube of Chaffin receives a code, which is not fully unique. Such a code may be different from other codes for that specific laboratory or hospital for a limited period of time. If two different hospitals or laboratories use the same system, they cannot exchange probes or containers for performing different analyses. The examiner respectfully disagrees. First, the present claims do not recite the code being used in two different hospitals or laboratories. The preamble of the claim recites, “A method for data management for **an analytical laboratory**...” Second, the identification code for each container, which is already unique, is combined with a unique patient code in memory 13. The combined code is also another unique code. Therefore, Chaffin reference does disclose a container with a unique identification code that may be used in an analytical laboratory.

Accordingly, claims 1-3, 5, 6, 8-12 remain rejected. The Arguments regarding claims 13 and 17 are moot since the claims are now cancelled.

**Rejections under 35 U.S.C. § 103 (a)**

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Regarding argument on page 17, the Examiner has fully discussed the advantages of applying an identification code during the production process or packaging by combining the teachings of Chaffin reference with that of Knepple et al. (WO 99/41044) in the previous Office Action. Page 9 of the previous Office Action, mailed August 13, 2003, discloses the motivation and the advantages of combining the teachings of Knepple with Chaffin reference to eliminate the possibility of erroneously mixing the identification code label with a corresponding container.

Accordingly, claims 4 and 7 remain rejected. The arguments regarding claims 14, 15, 18 and 19 are moot since the claims are now cancelled.

**Newly added claims 21-28**

The new claims are rejected under 35 U.S.C. § 103(a). Carr et al. (USPN 5,888,825) reference cures the deficiency of the container lacking an expiry date. The teachings of Chaffin et al. in view of Knepple in combination of Carr reference fully disclose, teach, or fairly suggest the each and every features of the claimed invention.

Therefore, claims 1-3, 5-12, and 21-28 are rejected as discussed in this Office Action.

***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

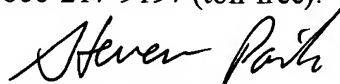
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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven S. Paik whose telephone number is 571-272-2404. The examiner can normally be reached on Mon - Fri (5:30am-2:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Lee can be reached on 571-272-2398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Steven S. Paik  
Examiner  
Art Unit 2876

ssp